

USPTO Form 1449 U.S. Department of Commerce  
Patent and Trademark Office

**Attorney Docket No.**  
**006050.00067**

107509627

## INFORMATION DISCLOSURE

### CITATION

Sheet 1 of 1

**Applicant(s):** WINGARD, et al.

**Filing Date: September 29, 2004**

**Group: TBA**

## U.S. PATENT DOCUMENTS

Examiner Initial	Patent No.	Date	Name	Class	Subclass	Filing Date (if appropriate)
/D.S./	6,362,234 B1	26 March 2002	HENDLER	514	109	

## FOREIGN PATENT DOCUMENTS

[illegible]

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)**

[illegible]

EXAMINER **Darryl Sutton**

Digitally signed by Darryl Sutton  
DN: cn=Darryl Sutton, c=US, o=USPTO, email=darryl.sutton@uspto.gov  
Date: 2007.11.29 13:31:06 -0500

DATE CONSIDERED 11/29/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Substitute for form 1449A/PTO

**(Use as many sheets as necessary)**

Sheet	1	of	5
-------	---	----	---

**Complete if Known**

<b>Application Number</b>	10/509,627
<b>Filing Date</b>	09/29/04
<b>First Named Inventor</b>	Peggy Wingard
<b>Art Unit</b>	TBD
<b>Examiner Name</b>	TBD
<b>Attorney Docket Number</b>	006050.00067

**JAN 26 2005**

[illegible][illegible]

**Examiner  
Signature**

## Darryl Sutton

Digitally signed by Darryl Sutton  
DN: cn=Darryl Sutton, c=US, o=USPTO, email=darryl.sutton@uspto.gov  
Date: 2007.11.29 15:21:38 -0500

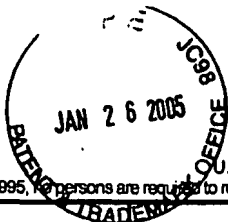
Date Considered

11/29/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.**



PTO/SB/08b(08-03)

Approved for use through 07/31/2008. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 5

**Complete if Known**

Application Number	10/509,627
Filing Date	09/29/04
First Named Inventor	Peggy Wingard et al.
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	006050.00067

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/D.S./		"Product Identification Guide," PDR, 52 Edition, 1998, Physicians' Desk Reference, pg. 343	
		"Zeneca Pharmaceuticals," PDR, 52 Edition, 1998, Physicians' Desk Reference, pgs. 3157-3163	
		AGALLOCO, JAMES, "Steam Sterilization and Steam Quality," January-February 2000, pgs. 59-63, Vol. 54, No. 1, Agalloco and Associates, Belle Mead, NJ	
		BALOUGH, VALÉRIA, PÉTIZON, MARCEL, and GOLFIER, MICHAEL, "Oxidations with Silver Carbonate/Celite. V. Oxidations of Phenols and Related Compounds," J. Org. Chem., 1971, pgs. 1339-1341, Vol. 36, No. 10, Laboratoire de Stéréochimie, Faculté des Sciences, 91 Orsay, France	
		BERNSTEIN, DAVID F., PhD, and HAMRELL, MICHAEL R., PhD, "Integrating Drug Supply Issues with Strategic Preclinical and Clinical Development," Drug Information Journal, 2000, pgs. 909-917, Vol. 34	
		BORCHERT, STEVEN J., RYAN, MICHELE M., DAVISON, RICHARD L., and SPEED, WILLIAM, "Accelerated Extractable Studies of Borosilicate Glass Containers," Research Article, March-April 1989, pgs. 67-79, Vol. 43, No. 2, The Quality Control Division, The Upjohn Company, Kalamazoo, Michigan and Crawley, United Kingdom	
		CACHET, TH., VAN DEN MOOTER, G., HAUCHECORNE, R., VINCKIER, C., and HOOGMARTENS, J., "Decomposition kinetics of erythromycin A in acidic aqueous solutions," International Journal of Pharmaceutics, 55, 1989, pgs. 59-65, Elsevier Science Publishers B.V. (Biomedical Division)	
		CONNORS, KENNETH A. and MOLLICA, JOSEPH A., JR., "Theoretical Analysis of Comparative Studies of Complex Formation, Solubility, Spectral, and Kinetic Techniques," Journal of Pharmaceutical Sciences, August 1966, pgs. 772-780, Vol. 55, No. 8	
		ERIKSSON, M., ENGLESSON, S., NIKLASSON F., and HARTVIG, P., "Effect of lignocaine and pH on propofol-induced pain," British Journal of Anaesthesia, 78, 1997, pgs 502-506	
		ERIKSSON, M., ENGLESSON S., and HARTVIG, P., "Acidified propofol retains its anaesthetic potency after storage," European Journal of Anaesthesiology, 16, 1999, pgs 166-168	
/D.S./		GRUBSTEIN, B. and MILANO, E., "Stabilization of Epinephrine in a Local Anesthetic Injectable Solution Using Reduced Levels of Sodium Metabisulfite and EDTA, Drug Development and Industrial Pharmacy, 18 (14), 1992, pgs 1549-1566, Marcel Dekker, Inc.	

Examiner Signature	Darryl Sutton <small>Digitally signed by Darryl Sutton DN: cn=Darryl Sutton, c=US, o=USPTO, email=darryl.sutton@uspto.gov Date: 2007.11.29 15:21:54 -0500</small>	Date Considered	11/29/2007
-----------------------	--	--------------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449B/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 5

## Complete if Known

Application Number	10/509,627
Filing Date	09/29/04
First Named Inventor	Peggy Wingard et al.
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	006050.00067

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/D.S./		HALL, JOHN C., FRACS, "Glycine," Review, November-December 1998, pgs. 393-397, Vol. 22, No. 6	
		HEM, STANLEY L., RUSSO, EMANUEL J., BAHAL, SURENDRA M., and LEVI, RALPH S., "Kinetic Analysis of Complex Formation between Penicillin and Sucrose," Journal of Pharmaceutical Sciences, February 1973, pgs. 267-270, Vol. 62, No. 2	
		KLEMENT, W., and ARNDT, J.O., "Pain on I.V. Injection of Some Anaesthetic Agents is Evoked by the Unphysiological Osmolality or pH of Their Formulations," British Journal of Anaesthesia, 66, 1991, pgs. 189-195	
		KLEMENT, W., and ARNDT, J.O., "Pain on Injection of Propofol: Effects of Concentration and Diluent," British Journal of Anaesthesia, 67, 1991, pgs. 281-284	
		KRISE, JEFFREY P., NARISAWA, SHINJI, and STELLA, VALENTINO J., "A Novel Prodrug Approach for Tertiary Amines. 2. Physicochemical and in Vitro Enzymatic Evaluation of Selected N-Phosphonoxyethyl Prodrugs," Journal of Pharmaceutical Sciences, September 1999, pgs. 922-927, Vol. 88, No. 9, American Chemical Society and American Pharmaceutical Association	
		LACHMAN, LEON, PAULI, WAYNE A., SHETH, PRAVIN B., and PAGLIERY, MIRIAM, "Lined and Unlined Rubber Stoppers for Multiple-Dose Vial Solutions II. Effect of Teflon lining on Preservative Sorption and Leaching of Extractives," Journal of Pharmaceutical Sciences, September 1986, pgs. 962-966, Vol. 55, No. 9	
		MARTIN, A.J., "pH-adjustment and discomfort caused by the intradermal injection of lignocaine," Forum, Anaesthesia, 1990, pgs 975-978, Vol. 45	
/D.S./		MENDENHALL, DOUGLAS W., Ph.D., "Stability of Parenterals," Drug Development and Industrial Pharmacy, 10(8&9), 1984, pgs 1297-1342, Marcel Dekker, Inc.	
		<del>BOYLAN, JAMES C. and EITES, ALAN J., "Parenteral Products," Drugs and the Pharmaceutical Sciences, Modern Pharmaceuticals, Second Edition, edited by Gilbert S. Benker and Christopher T. Rhodes, pgs. 491-536, Vol. 40</del>	
/D.S./		MORRIS, J.M., "Sterilisation Decision Trees Development and Implementation," Commentary, PDA Journal of Pharmaceutical Science & Technology, January-February 2000, pgs 64-68, Vol. 54, No. 1	
/D.S./		NISHINO, HIROSHI, ITOH NOBUYUKI, NAGASHIMA, MAKIKO, and KUROSAWA, KAZU, "Choice of Manganese(III) Complexes for the Synthesis of 4,4'-Biphenyldiols and 4,4'-Diphenylquinones," Bull. Chem., Soc. Jpn., 1992, pgs. 620-622, Vol. 65, No. 2	

Examiner  
Signature

Darryl Sutton

Digitally signed by Darryl Sutton  
DN: cn=Darryl Sutton, c=US, o=USPTO,  
email=darryl.sutton@uspto.gov  
Date: 2007.11.29 15:22:20 -0500

Date  
Considered

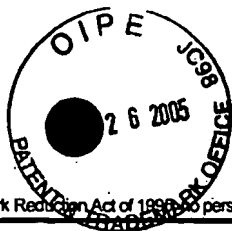
11/29/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/509,627
		Filing Date	09/29/04
		First Named Inventor	Peggy Wingard et al.
		Art Unit	TBD
		Examiner Name	TBD
		Attorney Docket Number	006050.00067
Sheet	4	of	5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/D.S./		PFLUG, IRVING J., and EVANS, KRISTEN D., "Carrying Out Biological Qualification, the Control Operation of Moist-Heat (Steam Sterilization) Processes for Producing Sterile Pharmaceuticals and Medical Devices," PDA Journal of Pharmaceutical Science & Technology, March-April 2000, pgs. 117-135, Vol. 54, No. 2	
		DELUCA, PATRICK P. and BOYLEAN, JAMES G., "Formulation of Small Volume Parenterals," Pharmaceutical Dosage Forms. Parenteral Medications, Volume 1, Second Edition, Revised and Expanded, Edited by Kenneth C. Aie, Herbert A. Lieberman, and Leon Lechman, pgs. 173-248	
/D.S./		PRANKERD, RICHARD and JONES, R. DOUGLAS, "Physicochemical compatibility of propofol with thiopental sodium," Am. J. Health-Syst. Pharm., November 1, 1996, pgs. 2606-2610, Vol. 53	
		REYNOLDS, DAN W., FACCHINE, KEVIN L., MULLANEY, JUNE F., ALSANTE, KAREN M., HATAJIK, TODD D., and MOTTO, MICHAEL G., "Available Guidance and Best Practices for Conducting Forced Degradation Studies," Pharmaceutical Technology, February 2002, pgs. 48-58	
		ROSEMAN, T.J., BROWN, J.A., and SCOTHORN, W.W., "Glass for Parenteral Products: A Surface View Using the Scanning Electron Microscope," Journal of Pharmaceutical Sciences, January 1976, pgs. 22-29, Vol. 65, No. 1	
		ROWE, R.C. WAKERLY, M.G. ROBERTS, R.J. GRUNDY, R.U. and UPJOHN, N.C., "Expert Systems for Parenteral Development," PDA Journal of Pharmaceutical Science & Technology, September-October 1995, pgs. 257-261, Vol. 49, No. 5	
		SOME, ISSA T., BOGAERTS, PHILIPPE, HANUS, RAYMOND, HANOCQ, MICHEL, and DUBOIS, JACQUES, "Stability Parameter Estimation at Ambient Temperature From Studies at Elevated Temperatures," Journal of Pharmaceutical Sciences, November 2001, pgs. 1759-176, Vol. 90, No. 11, Wiley-Liss, Inc. and the American Pharmaceutical Association	
		STEFFANSEN, BENTE and BUNDGAARD, HANS, "Erythromycin prodrugs: kinetics of hydrolysis of erythromycin and various erythromycin 2'-esters in aqueous solution and human plasma," International Journal of Pharmaceutics, 58, 1989, pgs. 159-168, Elsevier Science Publishers B.V. (Biomedical Division)	
		STRICKLEY, ROBERT G., "Parenteral Formulations of Small Molecules Therapeutics Marketed in the United States (1999) - Part I, PDA Journal of Pharmaceutical Science & Technology, November-December 1999, pgs. 324-349, Vol. 53, No. 6	
		STRICKLEY, ROBERT G., "Parenteral Formulations of Small Molecules Therapeutics Marketed in the United States (1999) Part II, PDA Journal of Pharmaceutical Science & Technology, January-February 2000, pgs. 69-96, Vol. 54, No. 1	
/D.S./		STRICKLEY, ROBERT G., "Parenteral Formulations of Small Molecules Therapeutics Marketed in the United States (1999) Part III, PDA Journal of Pharmaceutical Science & Technology, March-April 2000, pgs. 152-169, Vol. 54, No. 2	

Examiner Signature	Darryl Sutton	Digitally signed by Darryl Sutton DN: cn=Darryl Sutton, c=US, o=USPTO, email=darryl.sutton@uspto.gov Date: 2007.11.29 15:23:38 -0500	Date Considered	11/29/2007
--------------------	---------------	---	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449B/PTO

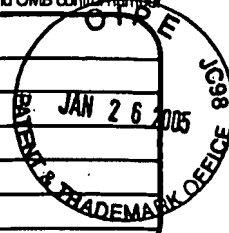
# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 5 of 5

## **Complete if Known**

Application Number 10/509,627  
 Filing Date 09/29/04  
 First Named Inventor Peggy Wingard et al.  
 Art Unit TBD  
 Examiner Name TBD  
 Attorney Docket Number 006050.00067



## **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/D.S./		TEMPLETON, ALLEN C., R.-HAN, YIENG-HAU, MAHAJAN, REJIV, CHERN, REY T., and REED, ROBERT A., "Rapid Headspace Oxygen Analysis for Pharmaceutical Packaging Applications," Pharmaceutical Technology, July 2002, pgs. 44-61	
		UGWU, SYDNEY, O. and APTE, SHIREESH P., "Systematic Screening of Antioxidants for Maximum Protection Against Oxidation: An Oxygen Polarograph Study," PDA Journal of Pharmaceutical Science & Technology, September-October 1999, pgs. 252-259, Vol. 53, No. 5	
		VINCKIER, C., HAUCHECORNE, R., CACHET, TH., VAN DEN MOOTER, G., and HOOGMARTENS, J., "A new mechanism for the decomposition of erythromycin A in acidic aqueous solutions," International Journal of Pharmaceutics, 55, 1989, pgs. 67-76, Elsevier Science Publishers B.V. (Biomedical Division)	
		YU, ANDREW B.C. and PORTMANN, GLENN A., "Oxidation Kinetics of an Antiasthmatic, 2-[(4-Hydroxyphenyl)amino]-5-methoxybenzenemethanol, and Stabilization with Ascorbic Acid," Journal of Pharmaceutical Sciences, October 1990, pgs. 913-915, Vol.79, No. 10, American Pharmaceutical Association	
/D.S./		YUCHA, CAROLYN B., HASTINGS-TOLSMAN, MARIE, and SZEVERENYI, NIKOLAUS M., "Differences Among Intravenous Extravasations Using Four Common Solutions," Journal of Intravenous Nursing, September-October 1993, pgs. 277-281, Vol. 16, No. 5	

Examiner Signature	Darryl Sutton <small>Digitally signed by Darryl Sutton DN: cn=Darryl Sutton, c=US, o=USPTO, email=darryl.sutton@uspto.gov Date: 2007.11.29 15:23:57 -0500</small>	Date Considered	11/29/2007
--------------------	--	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.  
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it contains a valid OMB control number.

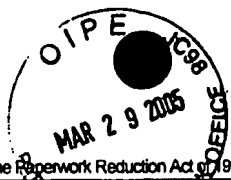
Substitute for form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/509,627
				Filing Date	09/29/2004
				First Named Inventor	Peggy Wingard et al.
				Art Unit	TBD
				Examiner Name	TBD
				Attorney Docket Number	006050.00067
Sheet	1	of	2		

[illegible][illegible]

Examiner Signature	Darryl Sutton	Digitally signed by Darryl Sutton DN: cn=Darryl Sutton, o=US, ou=USPTO, email=darryl.sutton@uspto.gov Date: 2007.11.29 15:16:34 -0500	Date Considered	11/29/2007
-----------------------	---------------	--	--------------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



PTO/SB/08b(08-03)

Approved for use through 07/31/2008. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 2

**Complete if Known**

Application Number	10/509,627
Filing Date	09/29/2004
First Named Inventor	Peggy Wingard et al.
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	006050.00067

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/D.S./		SHAO, XINLI; LI, HONG; WHITE, PAUL F.; KLEIN, KEVIN W.; KULSTAD, CHRISTINE; AND OWENS, ANDREW, "Bisulfite-Containing Propofol: Is it a Cost-Effective Alternative to Diprivan™ For Induction Of Anesthesia?," Anesthesia and Analgesia, vol. 91, October 2000, pgs. 871-875	
		<del>PARINOTTI, R., "Interactions physicochimiques et mode de conservation de Diprivan®. Physicochemical interactions and mode of storage of Diprivan®, Annales Françaises D'Anesthésie et de Réanimation, Masson, Paris, France, vol. 49, no. 4, 1994, pgs. 452-459.</del>	
/D.S./		HAN, JIHONG; DAVIS, STANLEY S; AND WASHINGTON, CLIVE, "Physical properties and stability of two emulsion formulations of propofol," International Journal of Pharmaceutics, vol. 215, March 14, 2001, pgs. 207-220	
/D.S./		HART, B, "Diprivan: a change of formulation," European Journal of Anaesthesiology, vol. 17, 2000, pgs. 71-73	
/D.S./		MANGIAMELI, S.; CALABRESE, V.; CANTARELLA, G.; MILAZZO, G.; NICOLOSI, D.; AND RIZZA, V., "Compatibility of reduced glutathione (GSH) with different solutions currently used in anesthesia and reanimation," Minerva Anestesiologica, vol. 61, 1995, pgs 407-409	
/D.S./		CRAIG, DOUGLAS B., "Preservatives in propofol," Canadian Journal of Anesthesiology, vol. 45, no. 9, 1998, page 913	
/D.S./		LEKAMP, JONATHAN E., AND DOBESH, PAUL P., "Propofol and Too Much Sulfite?," Chest, vol. 118, no. 1, July 2000, page 277	
/D.S./		BAKER, MAX T., "Yellowing of metabisulfite-containing propofol emulsion," American Journal of Health-System Pharmacy, vol. 58, June 1, 2001, pgs 1042-1047	

Examiner  
Signature

Darryl Sutton

Digitally signed by Darryl Sutton  
DN: cn=Darryl Sutton, ou=US, ou=USPTO,  
email=darryl.sutton@uspto.gov  
Date: 2007.11.29 15:16:14 -0500

Date

Considered

11/29/2007

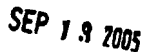
\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.





Approved for use through 07/31/2008. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**(Use as many sheets as necessary)**

Sheet	1	of	2
-------	---	----	---

**Complete if Known**

<b>Application Number</b>	<b>10/509,627</b>
<b>Filing Date</b>	<b>04/29/2005</b>
<b>First Named Inventor</b>	<b>Wingard et al.</b>
<b>Art Unit</b>	<b>1614</b>
<b>Examiner Name</b>	<b>TBD</b>
<b>Attorney Docket Number</b>	<b>006050.00067</b>

[illegible][illegible]

**Examiner  
Signature**

Darryl Sutton

Digitally signed by Darryl Sutton  
DN: cn=Darryl Sutton, o=US, ou=USPTO, email=darryl.sutton@uspto.gov

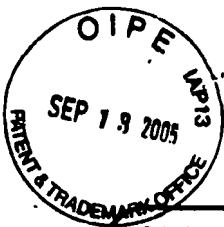
Date Considered

11/29/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

***If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.***



PTO/SB/08b(08-03)

Approved for use through 07/31/2008. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 2

**Complete If Known**

Application Number	10/509,627
Filing Date	04/29/2005
First Named Inventor	Wingard et al.
Art Unit	1614
Examiner Name	TBD
Attorney Docket Number	006050.00067

**NON PATENT LITERATURE DOCUMENTS**

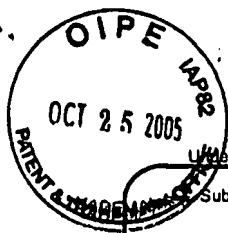
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/D.S./		Fechner, Jorg et al. "Pharmacokinetic Modeling of GPI 15715: A Watersoluble Prodrug of Propofol." 2002	
/D.S./		2001 Annual Meeting of the American Society of Anesthesiologists, New Orleans, LA, Oct. 13-17, 2001 (Anesthesiology Abstracts of Scientific Papers Annual Meeting, No. 2001, 2002, pages Abstract No. A-489 URL)	

Examiner Signature	Darryl Sutton	Digitally signed by Darryl Sutton DN: cn=Darryl Sutton, c=US, o=USPTO, email=darryl.sutton@uspto.gov Date: 2007.11.29 15:11:45 -05'00'	Date Considered	11/29/2007
-----------------------	---------------	---	--------------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08A (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number	10/509,627
Filing Date	4/29/2006
First Named Inventor	Peggy Wingard et al.
Art Unit	1614
Examiner Name	Jones, Dwayne C. Sutton
Attorney Docket Number	006050 00067

D.

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
/D.S./	A001	US- 2,829,151	4/1/1958	Britton et al.	
	A002	US- 3,271,314	9/6/1966	Ecke et al.	
	A003	US- 3,576,923	4/27/1971	Randell et al.	
	A004	US- 3,723,578	3/27/1973	Eiseman et al.	
	A005	US- 4,171,272	10/16/1979	Wright, R.	
	A006	US- 4,912,245	3/27/1990	Girardeau et al.	
	A007	US- 5,039,343	8/13/1991	Umeda et al.	
	A008	US- 5,091,211	2/25/1992	Richard, L.	
	A009	US- 5,110,503	5/5/1992	Cohen	
	A010	US- 5,120,464	6/9/1992	Kamegai et al.	
	A011	US- 5,554,576	9/10/1996	Mookerjee et al.	
	A012	US- 5,589,598	12/31/1996	Palocchi, M.	
	A013	US- 5,637,625	6/10/1997	Haynes, D.	
	A014	US- 5,646,176	7/8/1997	Golik et al.	
	A015	US- 5,723,538	3/3/1998	Fischer et al.	
	A016	US- 5,731,355	3/24/1998	Jones et al.	
	A017	US- 5,746,973	5/5/1998	Naraghi et al.	
	A018	US- 5,804,682	9/8/1998	Fischer et al.	
/D.S./	A019	US- 6,204,257	3/20/2001	Stella et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	B001	<del>DE 3000041</del>	<del>7/10/1990</del>			
	B002	<del>EP 252024</del>	<del>1/13/1988</del>			
/D.S./	B003	EP-324451	7/19/1989			
	B004	<del>EP 065410</del>	<del>4/25/1990</del>			
/D.S./	B005	EP-393579	10/24/1990			
/D.S./	B006	WO-9628603	9/19/1996			

Examiner  
Signature

Darryl Sutton

Digitally signed by Darryl Sutton  
DN: cn=Darryl Sutton, c=US, o=USPTO, email=darryl.sutton@uspto.gov  
Date: 2007.11.29 14:57:48 -0500

Date

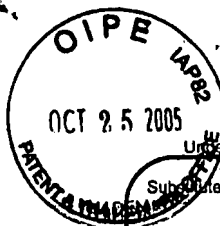
Considered

11/29/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/509,627		
		Filing Date	4/29/2005		
		First Named Inventor	Peggy Wingard et al.		
		Art Unit	1614		
		Examiner Name	Jones, Dwayne C. Sutton, D.		
Sheet	2	of	2	Attorney Docket Number	006050,00067

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/D.S./	C001	S. SAWADA et al., Synthesis and antitumor activity of A-ring or E. Lactone modified water-soluble prodrugs of 20(S)-camptothecin, including development of irinotecan hydrochloride trihydrate (CPT-11). Current Pharmaceutical Design, Vol. 1, No. 1, pp. 113-32 (1995).	
	C002	S. VARIA, University of Kansas, May 26, 1981, Ph.D. dissertation entitled "Water soluble prodrugs of 5,5-diphenylhydantoin."	
	C003	CHO, M.J. et al.: Metronidazole phosphate—a water-soluble prodrug for parenteral solutions of metronidazole. J. Pharm. Sci. vol. 71, pp. 410-4 (1982).	
	C004	VARIA, S.A. and STELLA, V.J.: Phenytoin prodrugs VI—In vivo evaluation of a phosphate ester prodrug of phenytoin after parenteral administration to rats. J. Pharm. Sci. vol. 73, pp. 1087-1090 (1984).	
/D.S./	C005	BUNDGAARD, H. Design of prodrugs: Bioreversible derivatives for various functional groups and chemical entities. In Design of prodrugs, edited by H. Bundgaard, Elsevier (1985).	

Examiner Signature	Darryl Sutton	<small>Digitally signed by Darryl Sutton DN: cn=Darryl Sutton, o=US, ou=USPTO, email=darryl.sutton@uspto.gov Date: 2007.11.29 14:57:20 -0500</small>	Date Considered	11/29/2007
--------------------	---------------	--	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Approved for use through 07/31/2008. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
to respond to a collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**Complete if Known**

**(Use as many sheets as necessary)**

Sheet	1	of	2
-------	---	----	---

<b>Application Number</b>	10/509,627
<b>Filing Date</b>	04/29/2005
<b>First Named Inventor</b>	Wingard et al.
<b>Art Unit</b>	1614
<b>Examiner Name</b>	<del>Jones, Dwayne G. Sutton, I</del>
<b>Attorney Docket Number</b>	006050.00067

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
/D.S./		WO 99/29640 A2	06-17-1999	EISAI CO. LTD.		
/D.S./		JP 04282390 A2 1991JP-0044977 1 (English Abstract)	10-07-1992 03-11-1991			

**Examiner  
Signature**

## Darryl Sutton

Digitally signed by Darryl Sutton  
DN: cn=Darryl Sutton, c=US, o=USPTO,  
email=darryl.sutton@uspto.gov  
Date: 2007.11.29 15:08:33 -05'00'

Date  
Considered

11/29/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not



Approved for use through 07/31/2008. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO

**(Use as many sheets as necessary)**

Sheet	2	of	2
-------	---	----	---

**Complete if Known**

<b>Application Number</b>	10/509,627
<b>Filing Date</b>	04/29/2005
<b>First Named Inventor</b>	Wingard et al.
<b>Art Unit</b>	1614
<b>Examiner Name</b>	Jones, Dwayne C. Sutton,
<b>Attorney Docket Number</b>	006050.00067

### NON PATENT LITERATURE DOCUMENTS

<b>Examiner Signature</b>	<b>Darryl Sutton</b> Digitally signed by Darryl Sutton DN: cn=Darryl Sutton, o=USPTO, email=darryl.sutton@uspto.gov Date: 2007.11.29 15:08:10 -0500	<b>Date Considered</b>	<b>11/29/2007</b>
-------------------------------	---	----------------------------	-------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

***If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.***

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Not for submission under 37 CFR 1.99)

Application Number	10509627
Filing Date	2005-04-29
First Named Inventor	Peggy Wingard et al.
Art Unit	1614
Examiner Name	<del>Dwayne C. Jones</del> Sutton, Darryl C.
Attorney Docket Number	006050.00067

**U.S. PATENTS**[Remove](#)

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

[Add](#)**U.S. PATENT APPLICATION PUBLICATIONS**[Remove](#)

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

[Add](#)**FOREIGN PATENT DOCUMENTS**[Remove](#)

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> j	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
/D.S./	1	1472793	GB		1977-05-04			<input type="checkbox"/>
/D.S./	2	0416232	EP	A2	1991-03-13			<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button.

[Add](#)**NON-PATENT LITERATURE DOCUMENTS**[Remove](#)**Darryl Sutton**

Digitally signed by Darryl Sutton  
 DN: cn=Darryl Sutton, o=US, o=USPTO,  
 email=darryl.sutton@uspto.gov  
 Date: 2007.11.29 14:43:36 -05'00'

11/29/2007

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

( Not for submission under 37 CFR 1.99)

Application Number	10509627
Filing Date	2005-04-29
First Named Inventor	Peggy Wingard
Art Unit	1614
Examiner Name	<del>Jones, Dwayne E.</del> Sutton, Darryl C.
Attorney Docket Number	006050.00067

**U.S. PATENTS**[Remove](#)

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

[Add](#)**U.S. PATENT APPLICATION PUBLICATIONS**[Remove](#)

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

[Add](#)**FOREIGN PATENT DOCUMENTS**[Remove](#)

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> j	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	<del>P0500430</del>	<del>HU</del>	<del>A</del>	<del>2005-08-20</del>	<del>MGL GP, Inc.</del>		<input type="checkbox"/>
/D.S./	2	03057153	WO	A2	2003-07-17	Guilford Pharmaceuticals, Inc.		<input type="checkbox"/>
	3	<del>2003057153</del>	<del>WO</del>	<del>A3</del>	<del>2003-07-17</del>	<del>Guilford Pharmaceuticals, Inc.</del>		<input type="checkbox"/>



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10509627
Filing Date	2005-04-29
First Named Inventor	Peggy Wingard
Art Unit	1614
Examiner Name	<del>Jones, Dwayne G.</del> Sutton, Darryl C.
Attorney Docket Number	006050.00067

/D.S./	4	9629064	WO	A1	1996-09-26	Zeneca Limited	<input type="checkbox"/>
	5	<del>P0702400A</del>	<del>HU</del>		<del>1998-03-30</del>	<del>AstraZeneca AB</del>	<input type="checkbox"/>
/D.S./	6	0008033	WO	A1	2000-02-17	The University of Kansas	<input type="checkbox"/>
	7	<del>P0200317A</del>	<del>HU</del>		<del>2007-01-12</del>	<del>The University of Kansas</del>	<input type="checkbox"/>
	8						<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1		<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature	Darryl Sutton	<small>Digitally signed by Darryl Sutton DN: cn=Darryl Sutton, o=US, ou=USPTO, email=darryl.sutton@uspto.gov Date: 2007.11.29 14:06:11 -0500</small>	Date Considered	11/29/2007
--------------------	---------------	--	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.